



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Inventors: Arjunan Ganesh, et al

For: Oropharyngeal Airway

Examiner: Ali, Shumaya B.

Art Unit: 3743

Atty Doc. No.: 149-06

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**Declaration of Dr. Richard H. Epstein Under 37 C.F.R. §1.132**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1560

1. I, Richard H. Epstein, MD, am a Professor of Anesthesiology at Jefferson Medical College of Thomas Jefferson University Hospital, the assignee of the above patent application for the above-identified invention. I have been a faculty member in the Department of Anesthesiology at Jefferson Medical College for 21 years.
2. I have no economic interest in the invention nor in any patent granted thereon.
3. A true and correct copy of my Curriculum Vitae showing my Educational Background, Fellowship Appointments, Postgraduate Training, Faculty Appointments, Hospital and Administrative Appointments, Specialty Certifications, Licensure, Awards, Honors and Memberships in Honorary Societies, Memberships in Professional and Scientific Societies, Academic Committees, Major Teaching and Clinical

Responsibilities, Funded Research, Invitational Lectures, Bibliography, Abstracts, Editorials, Reviews and Chapters, and other contributions is attached hereto.

4. I have extensive experience over 25 years in administering anesthesia during medical procedures and in using anesthesia devices. Additionally, I have authored or co-authored many professional articles dealing with anesthesia and patient care, as are listed in my Curriculum Vitae.

I believe that I am qualified as an expert in the field of anesthesia methods and devices for patient treatment.

5. I am familiar with the invention of this patent application, including amended claim 1 attached hereto. I am also familiar with endotracheal intubation devices of the types referred to in the following patents/patent applications:

Christopher Pub. No. U.S. 2002/0108610A

Greenberg U.S. patent No. 5,976,072

6. In both Christopher and Greenberg, as with all endotracheal intubation devices, the intubation tube extends well into the trachea, which creates tracheal stimulation, well below the location of the epiglottis. A laryngeal mask, as depicted in Fig. 10, for example, of Christopher, engages and stimulates the laryngeal inlet and the epiglottis. These systems are intended for use with a deep level of anesthesia, for substantial operations in which the patient is intended to be deeply anesthetized and during which, in many cases, mechanical ventilation is provided.

7. The device of the present invention of this application is for an entirely different purpose. It is for use where deep anesthetization is neither necessary nor desirable and where the patient always breathes by himself, where treatment is on an ongoing basis. For example, when a patient, often a child, is to receive periodic radiation treatment for treatment of a malignancy, each of short duration, but repeated over a substantial period of time, it would be highly undesirable to subject the patient to repeated tracheal or

laryngeal stimulations. Indeed, repeated stimulation itself can cause damage to the patient.

Thus, where a light level of anesthesia is to be used on a patient, especially on a repeated basis, such as during radiation treatment, repeated tracheal or laryngeal stimulation of the patient is not at all desirable.

8. The present invention, which is directed to a device for insertion into the mouth of a patient above and spaced from the epiglottis, avoids such tracheal and laryngeal stimulation, while allowing the administration of sufficient anesthesia, while simultaneously monitoring the patient and providing a source of oxygen, to perform the radiation treatments without causing damage to the patient through such stimulation.

The present invention has nothing to do with tracheal intubation, as do Christopher and Greenberg.

9. In my opinion, it would not be obvious to one skilled in the anesthesia method and device art to use any of the devices of the Christopher and/or Greenberg types for insertion into the mouth of a patient above and spaced from the epiglottis while the allowing the administration of sufficient anesthesia to perform radiation and like treatments, where repeated treatments are necessary, potentially causing damage to the patient through tracheal or laryngeal stimulation. In fact, the disclosures of Christopher and Greenberg actually teach away from any suggestion of arriving at a device as is set forth in amended claim 1 attached hereto. Moreover, in my opinion, it would not be obvious to modify the devices of Christopher or Greenberg to be sized so as to meet the requirements of claim 1 attached hereto. In fact, if one were to seek to shorten the devices of Christopher or Greenberg, in order to try to achieve the benefits of the present invention as set forth in claim 1 attached hereto, the devices of Christopher and Greenberg would not function in accordance with the needs of Christopher or Greenberg; which are allowing for a deep level of anesthetization of the patient, so that the patient will remain immobile while invasive procedures and/or operations are being carried out. That is, without having the deeper endotracheal intubation that is inherent with the devices of Christopher and Greenberg, the necessary deeper level of anesthetization

required for inserting tubes through those devices down into the trachea would not be possible. (See the illustration of the various conducting passages set forth in the photocopy of the conducting passages of a trachea, attached hereto.)

10. Also, in the device of the present invention, the feature of having a permanent additional conduit for suctioning is highly desirable. Based upon my experience treating pediatric patients, during radiation treatment, the medical personnel are necessarily located remote from the patient, in a separate room, due to the intense levels of ionizing radiation produced. However, in devices of the Christopher type as described on page 3, paragraph 0039, an anesthesiologist must be in immediate contact with the patient and additional lumens or catheters can be inserted down existing ducts. Such is quite different than having a conduit for the express purpose of suctioning, that can be used when the treating physician is remotely located from the patient and unable to access the patient airway during the course of the radiation treatment. Christopher is not suitable for maintaining an airway without intubating, or to stay in place if the patient is not being directly attended by someone close to the patient.

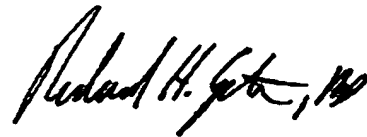
11. I have observed others using devices made in accordance with this invention. From taking care of pediatric patients requiring daily anesthetics to allow administration of radiation for malignant lesions, I am personally aware of the problem of cumulative trauma to the upper airway from repeated insertions of a laryngeal mask airway. Such a device frequently causes abrasions to the pharyngeal structures, resulting in bleeding and subsequent sore throats. The device described in this patent application identified above would very likely greatly reduce the incidents of such problems, as insertion of an oral airway rarely results in any trauma. For this reason, availability of such a device, which is not likely to be realized without patent protection, would represent a significant improvement to patient care and safety. In my opinion, based upon my personal experience, there has been a need for such a device, for a long time, but, based upon my experience, that need has been unfulfilled until the development of the present invention. While I have used other devices, many of the type of Christopher and/or Greenberg, such have not met the needs that are addressed by the present invention, where a light level of

anesthesia is desired without invading and stimulating the trachea or larynx where repeated anesthetizations are necessary, such as, with patients who are undergoing repeated radiation or the like. Other devices that are available fail to meet this need that is met by the present invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

11/10/2006

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Date

A handwritten signature in black ink, appearing to read "Richard H. Epstein, M.D.", written over a horizontal line.

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Richard H. Epstein, M.D.



## Curriculum Vitae

**Richard H. Epstein, MD**

**Date: April 6, 2006**

**Home Address:**

356 Holmecrest Road  
Jenkintown, PA 19046

**Office Address:**

Thomas Jefferson University Hospital  
111 S. 11<sup>th</sup> Street  
Suite 5480G  
Philadelphia, PA 19107

**Education:**

1971-74	B.A., University of Pennsylvania (Biochemistry)
1974-79	M.D., University of Pennsylvania School of Medicine

**Postgraduate Training and Fellowship Appointments:**

1979-80	Intern in Pediatrics, St. Christopher's Hospital for Children, Philadelphia
1980-82	Resident in Pediatrics, St. Christopher's Hospital for Children, Philadelphia
1982-84	Resident in Anesthesiology, Temple University Hospital, Philadelphia
1984-85	Fellow in Pediatric Anesthesia and Critical Care, Children's Hospital of Philadelphia, Philadelphia

**Faculty Appointments:**

1985-92	Instructor in Pediatrics Jefferson Medical College Thomas Jefferson University
1985-86	Instructor in Anesthesiology Jefferson Medical College Thomas Jefferson University
1986-92	Assistant Professor in Anesthesiology, Jefferson Medical College Thomas Jefferson University
1992-2004	Associate Professor in Anesthesiology, Jefferson Medical College

Thomas Jefferson University

2004-present    Professor in Anesthesiology  
Jefferson Medical College  
Thomas Jefferson University

Hospital and Administrative  
Appointments:

1985-2000    Division Director, Pediatric Anesthesiology,  
Thomas Jefferson University Hospital

Specialty Certification:

1984    American Board of Pediatrics  
1985    American Board of Anesthesiology  
1993    CDQ, American Board of Anesthesiology  
2002    CDQ, American Board of Anesthesiology  
2002    Certificate of Proficiency in Health  
Information Management Systems, Health  
Information Management Systems Society

Licensure:

New Jersey and Pennsylvania

Awards, Honors and Membership in Honorary Societies:

1973    Phi Beta Kappa, University of  
Pennsylvania  
1974    Honors Major in Biochemistry, Summa  
Cum Laude, University of Pennsylvania  
1974    General Honors Certificate, University of  
Pennsylvania  
1978    Dr. Roy G. Williams Research Award,  
University of Pennsylvania School of  
Medicine  
1994    Annual Research Prize (2<sup>nd</sup> Place), Society  
for Intravenous Anesthesia

**Memberships in Professional and Scientific Societies: (Include offices held.)**

**National Societies:**

1982-present	American Society of Anesthesiologists
1982-present	International Anesthesia Research Society
1987-present	Society for Pediatric Anesthesia
1988-present	Society for Technology in Anesthesia
1992-present	Society for Intravenous Anesthesia
2001-present	Healthcare Information and Management Systems Society

**Local Societies:**

1985-present	Philadelphia County Society of Anesthesiologists
1985-present	Pennsylvania Society of Anesthesiologists

**Editorial Positions:**

1982	Referee to Journal of Pediatrics
1993	Referee to Journal of Clinical Monitoring
1995-2001	Referee to Journal of Clinical Anesthesia
2003-present	Referee to Anesthesia & Analgesia
2005-present	Referee to Anesthesiology

**Academic Committees at Thomas Jefferson University and Affiliated Hospitals:**

2001-present	Member, JUP Information Technology Committee
2002-present	Member, JUP Practice Affairs Committee

**Major Teaching and Clinical Responsibilities at Thomas Jefferson University and Affiliated Hospitals:**

1. Anesthesia resident education
2. Medical student education
3. Attending Anesthesiologist
4. Administrator of Department of Anesthesiology web site on Pulse
5. Develop teaching/training programs for introduction of computerized clinical systems in the Department of Anesthesia
6. Support activities and processes within the business office of the Department of Anesthesia
7. Implementation of Anesthesia Information System



### Funded Research (Primary Investigator)

Ohmeda Corporation. Evaluation of the Finapres blood pressure monitor during general anesthesia. 1990

Ohmeda Corporation. Evaluation of the Finapres blood pressure monitor during controlled hypotension. 1991 (\$6,980 7/1/89-10/31/91)

Abbott Laboratories. Phase III clinical trial of sevoflurane in pediatric patients 1992-1993 (\$78,580 12/17/92-12/31/93)

Abbott Laboratories. Phase IV clinical trial of Fentanyl Oralet in pediatric patients, 1994-1995 (\$12,000 1/15/94-1/15/95)

Abbott Laboratories. Phase IV clinical trial of rapid vs. conventional induction of general anesthesia using sevoflurane in pediatric patients, 1996 (\$5,000 7/1/96-6/30/97))

Abbott Laboratories. Phase III clinical trial of sevoflurane vs. midazolam for sedation during regional and local anesthesia, 1997 (\$42,845 1/28/98 – 1/27/99)

Novamatrix. A comparison of thermodilution, the direct O<sub>2</sub> Fick technique, and a partial rebreathing CO<sub>2</sub> technique for the determination of cardiac output in patients undergoing mechanical ventilation, 1998 (\$13,760 1/21/98-4/1/98)

### Lectures by Invitation:

1. Clinical Issues in Outpatient Pediatric Anesthesia. 1st Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda. March, 1992
2. Pediatric Anesthesia Outside the OR. 1st Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 1992
3. Current Controversies in Outpatient Pediatric Anesthesia. Staten Island University Hospital. October, 1992
4. Sevoflurane in Pediatric Anesthesia. Yale University Department of Anesthesiology. February, 1994
5. Pharmacokinetic Control of Drug Infusions in Anesthesia. Yale University Department of Anesthesiology. February, 1994
6. Anesthesia by Autopilot: Are We Ready to Set the Cruise Control? Post-Graduate Assembly of the New York State Society of Anesthesiologists, December, 1994
7. Recognition, Treatment, and Prevention of Allergic Reactions to Latex. 1st Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 1996
8. Will Sevoflurane Replace Halothane in Pediatric Anesthesia?. 1st Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 1996

9. Current Controversies in Pediatric Anesthesia: Premeds, NPO, Colds. 1st Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 1996.
10. Laryngeal Mask Airways. 1st Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 1996.
11. Anesthesia Guide to the Internet. 5th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 1996
12. Use of the Laryngeal Mask Airway. 5th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 1996
13. Clinical and Pharmacological Properties of Sevoflurane. 5th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 1996
14. Pharmacokinetics for the Clinician. 5th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 1996
15. Automated Control of Muscle Relaxation. 1996 World Congress of Anesthesiologists. Sydney, Australia, 1996
16. Interpreting Effect Site Concentrations. Society for Intravenous Anesthesia. Cairns, Australia, 1996
17. Drug Infusions in Anesthesia. Grand Rounds, Mount Sinai Department of Anesthesiology, 1996
18. Adult Mask Induction with Sevoflurane. Colorado Society of Anesthesiologists Meeting, 1996
19. Sevoflurane Use in Pediatric Patients. Colorado Society of Anesthesiologists Meeting, 1996
20. Barnett/ParExel Conference on Electronic Data Capture, Atlanta, GA 1997
21. Barnett/ParExel Conference on Remote Data Entry, London, UK 1997
22. Utilize Electronic Signatures and "Paperless" Clinical Trials and Adhere to FDA Guidelines. IBC Conference on Superior Clinical Trials. Philadelphia, PA September, 1997
23. The Electronic Case Report Form: Design Considerations. DIA Conference on Case Report Form Design April, 1998
24. Practical Issues with Remote Data Entry Systems: A View from the Study Site. Barnett/ParExel Conference on Electronic Data Capture and Submissions. September, 1998
25. Minimizing the Timeline: The Impact of Adobe Portable Document Format (PDF) on CRF Design, Electronic Submission and Archiving. Barnett/ParExel Conference on Case Report Form Design. November, 1998
26. Identifying and Resolving "Suspicious" Data. Barnett/ParExel Conference on Electronic Data Management. May, 1999

27. Implications of HIPAA for Anesthesiologists and Anesthetists. 7th Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 2002.
28. Off Label Drug Use in Pediatric Anesthesia. 7th Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 2002
29. Optimization of Perioperative Staff. 7th Annual Jefferson Conference for Cross Country and Downhill Skiers. Big Sky, Montana, 2002
30. Real World Problems in the Analysis of Hospital IS Data. Annual Meeting of the Health Information Management Systems Society Meeting, San Diego, California, 2003
31. Residual Paralysis Following Neuromuscular Blockade: Is Quantitative Monitoring Necessary? 13th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 2004
32. Operational Decision Making Based on Operating Room Efficiency. 13th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 2004
33. What You Really Need to Know About HIPAA: A Brief Overview of the Privacy Rule for Anesthesia Care Providers. 13th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda March, 2004
34. Anesthesia Information Systems: why you should want one; how you should pick one. Annual Meeting Computers in Anesthesia , Lake Las Vegas, Nevada, 2004
35. How to Select an Anesthesia Information System. Practice Management Workshop CSA/USCD Annual Meeting, San Francisco, May, 2005
36. Return on Investment of an Anesthesia Information System. Practice Management Workshop CSA/USCD Annual Meeting, San Francisco, May, 2005
37. ROI of an Anesthesia Information System. Workshop on Operating Room Management. AACD Annual Meeting, New Orleans, March 2005
38. Anesthesia Information System: Coming Soon to an OR near You! 15th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda April, 2005
39. Update on Management and Reversal of Neuromuscular Blockade. 15th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda April, 2005
40. Update on Monitoring of Anesthetic Depth. 15th Annual Bermuda Shorts for Clinical Anesthesiologists. Bermuda April, 2005

## Bibliography:

Research Publications, peer reviewed (print or other media)

1. **Epstein RH**, Zeiger AV, Crocker C, Voet D. The X-ray crystal structure of the molecular complex 8-bromo-9-ethyladenine 5-allyl-5-isobutylbarbituric acid. *Acta Crystallographica*, Vol B 32, Part 7, July, 1976.
2. **Epstein RH**, Elkins WL. Studies of immunity to a transplantable murine neuroblastoma. *Progress in Cancer Research and Therapy*, Vol 12: 235-241, 1980.
3. Leighton BL, Norris MC, **Epstein RH**, Larijani GE. Limitations of epinephrine as a marker of intravascular injection in laboring women. *Anesthesiology* 66:688-691, 1987.
4. **Epstein RH**, Larijani GE, Wolfson PJ, Ala-Kokko TI, Boerner TF. Plasma bupivacaine concentrations following ilioinguinal-iliohypogastric nerve blockade in children. *Anesthesiology* 69: 773-776, 1988.
5. **Epstein RH**, Kaplan S, Leighton B, Norris MC, DeSimone CA. Evaluation of a continuous noninvasive blood pressure monitor in obstetric patients undergoing spinal anesthesia. *Journal of Clinical Monitoring* 5:157-163, 1989.
6. Check JH, **Epstein R**, Nowroozi K, Shanis BS, Wu CH, Bollendorf A. The hypo-osmolar swelling test as a useful adjunct to the semen analysis to predict fertility potential. *Fertility Sterility* 52(1): 159-161, 1989.
7. Check JH, Wu CH, **Epstein R**, Adelson HJ, Davies E, Liss J, Stern J, Vetter B. Effect of age on the success of therapy for infertility. *Infertility* 12(2):63-71, 1989.
8. Check JH, Vazze M, **Epstein R**, Wu CH, Quattrocchi J, Vetter B. 17-hydroxyprogesterone level as a marker for corpus luteum function in aborters vs nonaborters. *Intl Journal of Fertility* 35(2):112-115, 1990.
9. **Epstein RH**, Brummett RR, Lask GP. Incendiary potential of the flash-lamp pumped 585-nm tunable dye laser. *Anesth Analg* 71:171-5, 1990.
10. Nazari A, Check JH, **Epstein RH**, Dietterich C, Farzanfar S. Relationship of small-for-dates sac size to crown-rump length and spontaneous abortion in patients with a known date of ovulation. *Obstet-Gynecol.* 78:369-73, 1991.
11. **Epstein RH**, Huffnagle S, Bartkowski RR. Comparative accuracies of a finger blood pressure monitor and an oscillometric blood pressure monitor. *Journal of Clinical Monitoring* 7:161-167, 1991
12. Bartkowski RR, **Epstein RH**. Relationship between train of four ratio and first twitch depression during neuromuscular blockade: A pharmacokinetic/dynamic explanation. *Journal of Pharmacokinetics and Biopharmaceutics.* 18:335-346, 1990

13. **Epstein RH, Bartkowski RR, Huffnagle S.** Continuous noninvasive finger blood pressure during controlled hypotension. *Anesthesiology* 75:796-803, 1991.
14. **Goldberg ME, Epstein RH, Rosenblum F, Larijani G, Marr A, Lessin J, Torjman M, Seltzer J.** Do heated humidifiers and heat and moisture exchangers prevent temperature drop during surgery? *Journal of Clinical Anesthesia* 4:16-20, 1992
15. **Bartkowski RR, Goldberg ME, Huffnagle S, Epstein RH.** Sufentanil disposition. Is it affected by erythromycin? *Anesthesiology*. 78:260-5, 1993
16. **Epstein RH, Halmi BH.** Oxygen leakage around the laryngeal mask airway during laser treatment of port-wine stains in children. *Anesth Analg* 78:486-9, 1994
17. **Epstein RH, Mendel HG, Guarnieri KM, Staudt SR, Lessin JB, Marr AT.** Sevoflurane vs. halothane for general anesthesia in pediatric patients: A comparative study of vital signs, induction, and emergence. *J Clin Anesth* 7:237-244. 1995
18. **Epstein RH, Ferouz F, Jenkins MT.** Airway sealing pressures of the laryngeal mask airway in pediatric patients. *J Clin Anesth* 8:93-8, 1996
19. **Kataria B, Epstein RH, et. al.** Sevoflurane in Pediatric Patients. *Paediatric Anesth* [in press]
20. **Epstein RH, Mendel HG, Witkowski TA, Water R, Guarnieri, Marr AT, Lessin JB.** Safety and Efficacy of Oral Transmucosal Fentanyl Citrate for Preoperative Sedation in Young Children. *Anaesth Analg* 83:1200-5, 1996
21. **Epstein RH, Stein AL, Marr AT, Lessin JB.** High concentration vs. incremental induction of anesthesia with sevoflurane in children: a comparison of induction times, vital signs, and complications. *J Clin Anesth* 10: 40-45, 1998
22. **Epstein RH, Dexter F.** Economic analysis of linking operating room scheduling and materials management information systems for just-in-time inventory control. *Anesth Analg* 91:337-43, 2000
23. **Dexter F, Epstein RH, Penning DH.** Statistical analysis of post-anesthesia care unit staffing at a surgical suite with frequent delays in admission from the operating room – a case study. *Anesthesia & Analgesia* 92:947-949, 2001
24. **Dexter F, Epstein RH, Marsh HM.** Statistical analysis of weekday operating room anesthesia group staffing at nine independently managed surgical suites. *Anesthesia & Analgesia* 92:1493-1498, 2001
25. **Epstein RH, Dexter F.** Statistical power analysis to estimate how many months of data are required to identify operating room staffing solutions to reduce labor costs and increase productivity. *Anesthesia & Analgesia* 94:640-643, 2002

26. Dexter F, **Epstein RH**, HM Marsh. Costs and risks of weekend anesthesia staffing at six independently managed surgical suites. *Journal of the American Association of Nurse Anesthetists* 70: 377-381, 2002
27. **Epstein RH**, Dexter F. Uncertainty in knowing the operating rooms in which cases were performed has little effect on operating room allocations or efficiency. *Anesthesia & Analgesia* 95:1726-1730, 2002
28. **Epstein RH**, Dexter F, Traub RD. Statistical power analysis to estimate how many months of data are required to identify post anesthesia care unit staffing to minimize delays in admission from operating rooms. *Journal of PeriAnesthesia Nursing* 17(2):84-88, 2002
29. Abouleish AE, Dexter F, **Epstein RH**, Lubarsky DA, Whitten CW, Prough DS. Labor costs incurred by anesthesiology groups because of operating rooms not being allocated and cases not being scheduled to maximize operating room efficiency. *Anesthesia & Analgesia* 96:1109-1113, 2003
30. Dexter F, **Epstein RH**. Optimizing second shift OR staffing. *AORN Journal* 77(4) :825-830, 2003
31. Dexter F, Abouleish AE, **Epstein RH**, Whitten CW, Lubarsky DA. Use of operating room information system data to predict the impact of reducing turnover times on staffing costs. *Anesthesia & Analgesia* 97:1119-1126, 2003
32. Dexter F, **Epstein RH**, Traub RD, Xiao Y. Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453, 2004
33. Dexter F, **Epstein RH**, Traub RD, Xiao Y. Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453, 2004
34. Dexter F, Epstein RH, Traub RD, Xiao Y. Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453, 2004
35. Dexter F, **Epstein RH**, Traub RD, Xiao Y. Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453, 2004
36. Dexter F, **Epstein RH**, Abouleish AE, Whitten CW, Lubarsky DA. Impact of reducing turnover times on staffing costs. *Anesthesia & Analgesia* 98:872, 2004
37. Dexter F, **Epstein RH**, Ippolito GV. Practical application of research on operating room efficiency and utilization. In McLoughlin T, Lake C, Johnson J: *Advances in Anesthesiology* 22: 29-49, 2004
38. Dexter F, **Epstein RH**, de Matta R, Marcon E. Strategies to reduce delays in admission into a postanesthesia care unit from operating rooms. *Journal of PeriAnesthesia Nursing* 20(2): 92-102, 2005

39. Dexter F, Marcon E, **Epstein RH**, Ledolter J. Validation of statistical methods to compare cancellation rates on the day of surgery. *Anesthesia & Analgesia* 101: 465-473, 2005
40. Dexter F, **Epstein RH**, Marcon E, Ledolter J. Estimating the incidence of prolonged turnover times and delays by time of day. *Anesthesiology* 102: 1242-1248, 2005
41. Dexter F, **Epstein RH**. Operating room efficiency and scheduling. *Current Opinion in Anaesthesiology* 18: 195-198, 2005
42. Dexter F, Macario A, **Epstein RH**, Ledolter J. Validity and usefulness of a method to monitor surgical services' average bias in scheduled case durations. *Canadian Journal of Anesthesia* 52: 935-939, 2005
43. Dexter F, **Epstein RH**, de Matta R, Marcon E. Strategies to reduce delays in admission into a postanesthesia care unit from operating rooms. *Journal of PeriAnesthesia Nursing* 20(2): 92-102, 2005

Abstracts:

1. **Epstein RH, Elkins WL.** Genetic control of immunity to transplantable murine neuroblastoma. Abstracts of Scientific Papers. 1979 Annual Meeting of the American Association for Cancer Research, p. 178
2. **Jobes DR, Nicolson SC, Epstein RH, Campbell FW, Schwartz AJ, Norwood WI.** Hemodynamic response to rapid protamine administration in infants and children. Abstracts of Scientific Papers, 1986 Annual Meeting of the Society of Cardiovascular Anesthesiologists
3. **Leighton BL, Norris MC, Sosis M, Epstein R, Chayen B, Larijani GE.** Epinephrine can be an effective test dose in laboring patients. Abstracts of Scientific Papers. 1986 Annual Meeting of the Society of Obstetrical Anesthesia and Perinatology
4. **Leighton BL, Norris MC, Sosis M, Epstein R, Chayen B, Larijani GE.** Epinephrine test dose may not be safe in labor. Abstracts of Scientific Papers. 1986 Annual Meeting of the Society of Obstetrical Anesthesia and Perinatology
5. **Leighton BL, Norris MC, Sosis M, Epstein R, Larijani GE.** Limitations of an epinephrine epidural test dose in laboring patients. *Anesthesiology* 66:A403, 1986
6. **Epstein RH, Larijani GE, Wolfson P.** Bupivacaine concentrations following ilioinguinal-iliohypogastric nerve blocks in children. *Anesthesiology* 65:A429, 1986
7. **Mora CT, McNulty SE, Epstein RH.** Postoperative ventricular pacing using a new design pulmonary artery catheter. *Society of Cardiovascular Anesthesia: AIS4*, 1987
8. **Bartkowski RR, Epstein RH.** Train-of-four hysteresis: A pharmacokinetic and dynamic model. *J Clin Monit* 4:127, 1988
9. **Epstein RH, Bartkowski RR.** Computer/monitor interfacing via the RS232C protocol. *J Clin Monit* 4:136-137, 1988
10. **Epstein RH, Bartkowski.** Evaluation of a Continuous Blood Pressure Monitor During Deliberate Hypotension in Orthopedic Patients. *Anesthesiology* 69:A323, 1988
11. **Mora CT, Dudek C, Epstein R, Torjman M, White PF.** Comparison of Fentanyl to Thiopental and Propofol for Maintenance of Anesthesia During Cardiac Surgery. *Anesthesiology* 69:AS9, 1988
12. **Rosenblum F, Goldberg ME, Larijani GE, Jan RH, Epstein RH, Marr AT, Lessin JL, Seltzer JL.** Do Heated Humidifiers or Heat and Moisture Exchangers Really Prevent Temperature Drop during Surgery? *Anesthesiology* 69:A444, 1988
13. **DeSimone CA, Norris MC, Leighton B, Epstein R, Palmer C, Kaplan, Goodman D.** Spinal Anesthesia with Hyperbaric Bupivacaine for Cesarean Section: A Comparison of Two Doses. *Anesthesiology* 69:A670, 1988



14. Mora CT, Dudek C, **Epstein RH**, Torjman MC, White PF. A Comparison of Fentanyl, Enflurane, Thiopental and Propofol for Maintenance of Cardiac Anesthesia. Society of Cardiovascular Anesthesiologists 11th Annual Meeting p193, 1989
15. Weiss JA, Goldberg ME, Norris MC, Clark SK, **Epstein RH**, Marr AT, Seltzer JL. Atropine and Glycopyrrolate Do Not Inhibit the Effectiveness of Metoclopramide and Cimetidine in the General Surgical Population. *Anesthesia and Analgesia* 68:S304, 1989
16. Mora CT, Dudek C, **Epstein RH**, Torjman MC, White PF. Cardiac Anesthesia Techniques: Fentanyl Alone or in Combination with Enflurane or Propofol. *Anesthesia and Analgesia* 68:S202, 1989
17. Huffnagle SL, **Epstein RH**, Bartkowski RR. Comparison of Direct Arterial, Finapres, and Dinamap Blood Pressures. *Anesthesiology* 71:A40S, 1989.
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Alternative Media: *(Other non-peer reviewed contributions to alternative communication formats, such as instructional audio or video tapes, articles in the lay press, educational material via Internet, etc.)*

**Educational, Clinical, and Research Software**

1. **PK-SIM™** Pharmacokinetic simulation program to teach concepts of applied pharmacokinetics as applied to the practice of anesthesiology.
2. **Automated BIS Consultant™** Program interfaced with physiologic patient monitors to teach how to adjust anesthetic drug concentrations based on the Bispectral Index, a measure of anesthetic depth
3. **Merlin™** Real-time data collection program to facilitate collection of hemodynamic data from HP patient monitors for anesthesia research studies
4. **Twitcher™** Real-time data collection program used for neuromuscular blocking agent research studies
5. **JeffSprint™** Electronic medical record for preoperative assessments in the Patient Testing Center at Thomas Jefferson University Hospital
6. **JeffStaff™** Companion program to ORSOS patient scheduling system developed for TJUH to enter anesthesia staff information on the daily OR schedule
7. **CalcuatOR™** Software for optimization of surgical allocations and operating room staffing

Claim 1 (Currently Amended)      An oropharyngeal device for maintaining a patient airway without requiring endotracheal intubation, a laryngeal mask or a cuffed airway, wherein the device is adapted for insertion through the mouth of a patient and with one end into the ~~mouth~~ pharynx of a patient above and spaced from the epiglottis of the patient, and which allows an administering anesthesiologist to be distant from the patient during use, comprising:

a.      a body having a distal end and a proximal end, the body sized such that when the distal end of the body is inserted into the mouth of the patient until the proximal end is disposed outside and adjacent to the patient's mouth, the distal end is disposed within the pharynx above the epiglottis and at a distance from the epiglottis;

b.      at least one channel forming at least one airway in the device body extending between the proximal end and the distal end of the device body , with the channel have a proximate end and a distal end and with the channel sized to comprise means whereby the distal end is disposed within the pharynx above the epiglottis and at a distance from the epiglottis;

c.      at least one first conduit in the device body for conveying an inhalant gas to the patient that extends from the proximal end to the distal end of the device body and with said at least one first conduit including connection means at a proximal end of the device for providing inhalant gas, with the at least one first conduit having a proximal end and a distal end and with the at least one first conduit sized to comprise means whereby its distal end is disposed within the pharynx above the epiglottis and at a distance from the epiglottis;

d.      at least one second conduit for suctioning that extends from the proximal end to the distal end of the device body and with said at least one second conduit including connection means at a proximal end of the device for suctioning, with the at least one second conduit having a proximal end and a distal end and with the at least one second conduit sized to comprise means whereby its distal end is disposed within the pharynx above the epiglottis and at a distance from the epiglottis; and

e. at least one third conduit for sampling gas exhaled by the patient that extends from the proximal end of the device body and terminates at a position in the channel and with said at least one third conduit including connection means at a proximal end of the device for withdrawing sampling gas, with the at least one third conduit having a proximal end and a distal end and with the at least one third conduit sized to comprise means whereby its distal end is disposed above the epiglottis and at a distance from the epiglottis;

f. whereby the sizing of the device and its channel and conduits to terminate above the epiglottis and at a distance from the epiglottis avoids manipulation of the larynx and subglottic structures during use; and

g. wherein the first, second and third conduits comprise means whereby administration of inhalent gas, suctioning and the sampling of gas exhaled by the patient may take place simultaneously through separate conduits.

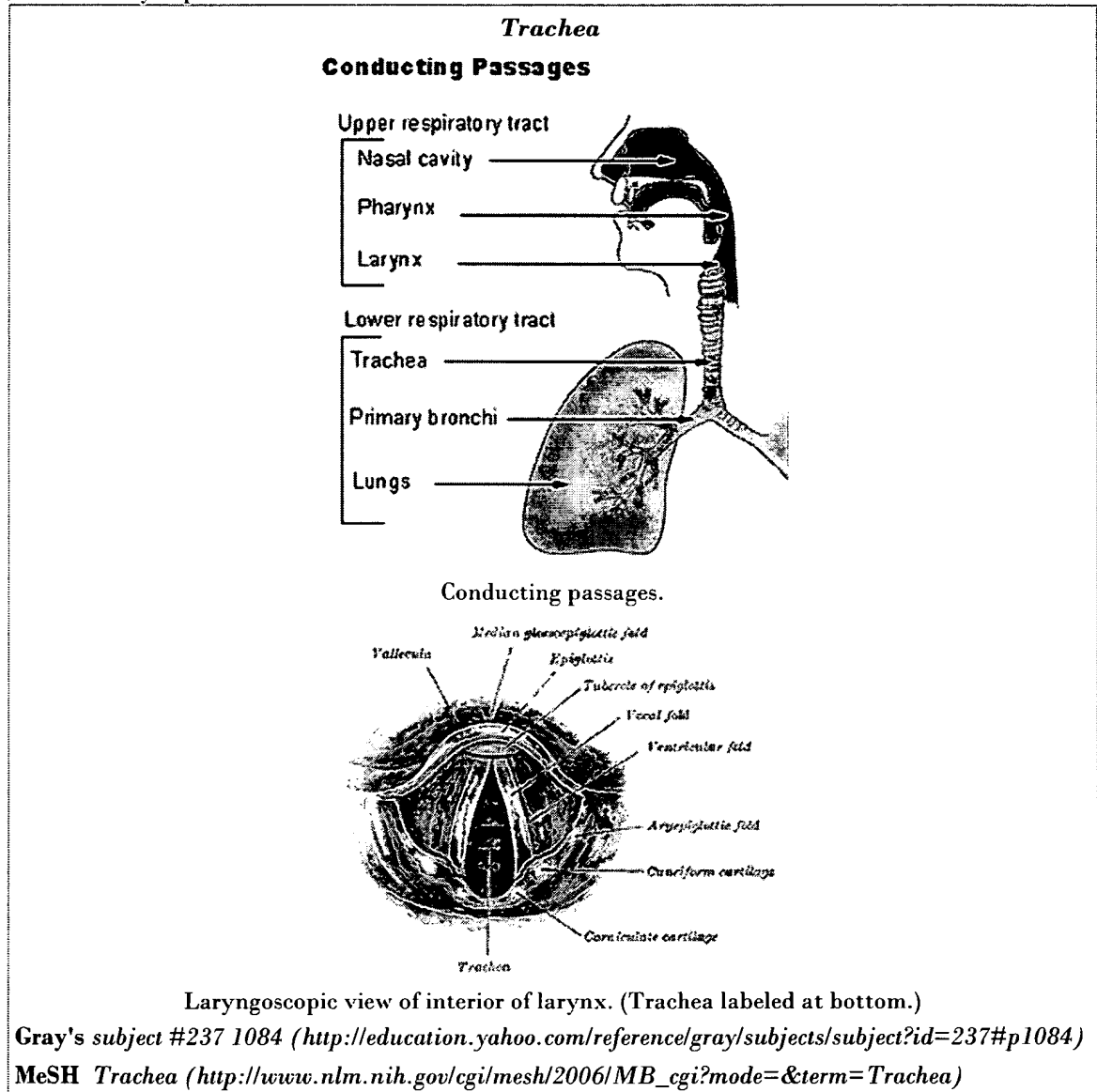


# Trachea

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**Trachea** (IPA: [ˈtreɪkiə]) is a common biological term for an airway through which respiratory air transport takes place in organisms. In terrestrial vertebrates, such as birds and humans, the trachea lets air move from the throat to the lungs. In terrestrial



invertebrates, such as onychophorans and insects, tracheae conduct air from outside the organism directly to all internal tissues.

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